1 262 146

PATENT SPECIFICATION

(11) 1 262 146

DRAWINGS ATTACHED

(21) Application No. 11368/69 (22) Filed 4 March 1969

(31) Convention Application No. 710609 (32) Filed 5 March 1968 in

(33) United States of America (US)

(45) Complete Specification published 2 Feb. 1972

(51) International Classification F 04 b 21/02

(52) Index at acceptance

F1A 4L 4S3 4S4 4SX
A5R 33C1A 33C4
F2G 14B 1E
F2V J2B

(54) TWIN VALVE CONNECTOR

(71) We, PALL CORPORATION, a corporation organised and existing under the laws of the State of New York, United States of America, and having a principal place of business at 30 Seacliff Avenue, Glen Cove, New York, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to an improved check valve assembly, in the form of a twin valve connector, for use in the administration of medicaments, for injecting fluids into or withdrawing fluids from the body, and more particularly, a twin valve connector for use with syringes, for example with the syringe pumps described in British Patent Specification No. 1,232,655, in injecting into or removing from the body a volume of fluid greater than the capacity of the syringe.

Syringes are widely used in medicine for the injection of fluids into the body, or for withdrawal of fluids from the body. Frequently, the volume of fluid that is to be injected or withdrawn is greater than the available capacity of the syringe. This requires two or more injections or withdrawals, with a corresponding number of insertions of the syringe needle into the body.

In order to avoid this problem, Y-couplings have been provided, such as are described in U.S. patent No. 986,263 to Bevill, patented March 7, 1911, which permits the connection of the syringe to an additional reserve container. The coupling is provided with valves, to regulate the flow of fluid in the proper direction, and prevent any backflow thereof, and these valves are connected with the Y-coupling by a section of flexible tubing. This device is large and clumsy, however, and has never been widely employed, partly because it is really only useful with syringes of very large volume, whereas the problem most frequently is encountered when the syringes have a very small volume. In such cases, the Bevill device is virtually useless.

In accordance with the invention, a twin valve connector is provided, which combines in one unit a coupling body having three passages therethrough that are interconnected, and two check valves, one each in two of the passages, ensuring that flow of fluid through such passages of the connector proceeds only in one direction. The connector is in one unit, having one or a plurality of parts that are fitted and secured together in a unit construction, with the valves fixed in the two passages therein in a leak-tight manner, and lends itself to fabrication by molding or casting to a predetermined shape. This not only simplifies the manufacture of the T-connector, but also makes it suitable for mass production, and thus reduces its cost to a minimum.

In a preferred embodiment of the device, the coupling is made entirely of plastic, with the exception of the check valves, which can be of a plastic or rubber material, and the plastic components of the coupling are all united together, with the check valves locked in position, and with mating and/or standard fittings, joints or sockets in each of the three passages, for coupling thereof to a syringe of conventional construction, a delivery means, and a receptacle or fluid supply. A preferred type of mating joint or socket is a Luer fitting or Luer-Lok (Registered Trade Mark).

According to the present invention there is provided a twin valve connector for coupling a syringe to a liquid medicament supply or a fluid receptacle, for delivery to or removal from a body via a fluid delivery device of a volume of liquid medicament or body fluid, respectively in excess of the capacity of the syringe, comprising, a coupling body of plastics material having three interconnected passages therethrough, check valves in two of said passages controlling flow of fluid therethrough in a single direction, the check valves having retaining means at an outer peripheral portion thereof, a fitting insert in each valve-containing passage, each fitting

insert comprising a plastics material, the fitting insert extending into the said passage from the outside of the coupling body, and having a central passage therethrough for passage of fluid into and out from the connector, said valve retaining means being retained by the fitting insert and/or the coupling body and a peripheral portion of the fitting insert closely abutting an inner wall of the passage, and being either integrated with the plastics material of the coupling body, thereby obliterating any seam therebetween at that portion, or being bonded with the material of the coupling body, and forming a leaktight barrier, the fitting insert thus being retained in the coupling body in a permanent leaktight fit, and means at an outer portion of each passage adapted for connection of said passage and the coupling body to a liquid medicament supply container, or a fluid receptacle, or a fluid delivery device or a syringe.

A feature of the connector according to the invention is its extremely small internal volume or fluid retention. This is usually less than 1 cc., and is preferably less than 0.1 cc. This means that quite high operating pressures can be achieved using conventional medical syringes, and also that very little of the fluid being delivered or withdrawn is wasted within the connector.

A further feature is that it can be made of a rigid, non-pressure - deformable material, which means that none of the available fluid pressure delivered via the syringe is lost in distending the connector.

Figure 1 is a view in cross-section of a typical twin valve connector in accordance with the invention, employing duck-bill check valves;

Figure 2 is an end view, taken along the line 2-2 of Figure 1, and looking in the direction of the arrows;

Figure 3 is a view in cross-section of another embodiment of connector, employing umbrella valves; and

Figure 4 is a view in cross-section of another embodiment of connector, employing flap valves.

In the drawings, like numbers refer to like parts.

The twin valve connector shown in Figure 1 has a coupling housing 1 that is molded in one piece entirely of plastics material, in this case, a modified phenylene oxide resin, sold commercially under the trade name NORYL (Registered Trade Mark). However, other thermoplastic or thermosetting moldable or castable plastics materials can be employed, such as ethyl cellulose, cellulose acetate-butyrate, cellulose propionate, nylon, polyphenylene oxide, polyethylene, polypropylene, polytetra - fluoroethylene (Teflon, Registered Trade Mark), Polychlorotrifluoroethylene (Kel-F, Registered Trade Mark), polystyrene, polyvinyl chloride, polycarbonates, polyoxymethylene (Delrin, Registered Trade Mark), epoxide resins, urea-formaldehyde, melamine-formaldehyde, phenol-formaldehyde, 2 - methyl - pentene polymers, (TPX), and polyester resins.

The coupling body constitutes a unit made in three pieces, the housing 1, and two fitting inserts 2 and 3, all of which, as shown in the Figures, are bonded together or integrated together with a solvent, at their adjoining contacting surfaces. The coupling housing 1 as shown is in a T-shape, with three legs, 4, 5, 6, each of which bears a central passage 7, 8, 9, respectively, meeting at central chamber 30 of the housing. A T-shape has been adopted for convenience, but it will be evident that the configuration of the coupling is in no way critical. The three passage-bearing legs thereof can be set in the angles of a Y, or at any desired angle other than the 90° angle shown in Figure 1. The 90° angle is preferred, however, for reasons that will be apparent from the following discussion.

The central passages 7, 8 and 9 intersect at the center of the coupling housing. The coupling housing 1 at the inner end of the passage 8 has a reentrant portion 10 that defines a valve seat 11. Beyond the valve seat 11 is a wide bore 12 that extends to the exterior of the housing. A check valve of the duckbill type is placed at the inner end of the bore 12 with the duckbill 18 facing outwardly from the valve seat 11, and with a base flange 16 abutting against the valve seat 11 in a leak-tight seal. The valve can be of any resilient or flexible heat-, water-, and solvent-resistant material, such as natural or synthetic rubber, for example, neoprene, or butadiene - styrene - acrylonitrile polymer, polypropylene, polyethylene, ethylene-propylene polymers, polyvinyl chloride or rubber hydrochloride resin. The base flange 16 of the valve is locked in position in the valve seat 11 by the fitting insert 2, which fits snugly in the bore 12 with its external wall bonded thereto or integrated therewith.

It will be appreciated that the fitting insert 2 can be held in the bore 12 by a press fit, or the sides of the bore and the fitting insert 2 can be correspondingly threaded so that they can be screwed tightly together, prior to bonding or integration. The fitting holds the flange 16 of the valve 15 tightly against the valve seat 11 in a leak-tight seal.

It will be evident that the check valve 15 ensures that flow in the passage 8 is only in the direction shown by the arrow.

The fitting 2 has a central passage 17 connecting at its inner end with passage 28 through the check valve 15. The outer end portion of the fitting 2 is provided with a male Luer fitting 13 to mate with a Luer

tipped needle N or other fluid delivering or withdrawing device.

At the inner end of the passage 9 in arm 6, the housing 1 is formed with a reentrant portion 20, defining at its outer end a valve seat 21, against which is seated a flange 22 of a check valve 23, also of the duckbill type. This check valve faces inwardly, so that flow in the passage 9 proceeds only in the direction shown by the arrow.

Beyond the valve seat 21, the housing 1 widens, and defines a bore 24 extending to the exterior of the housing 1. Held within the bore in a snug fit is the fitting insert 3, the inner end of which abuts against the exterior face of the flange 22 of the check valve 23, and holds it tightly in position against the valve seat 21, in a leaktight seal. The fitting insert 3 has an internal passage 27 through the check valve, and this passage at its exterior portion 26 has a female Luer fitting 19 for reception of a tubing or other connector leading from a fluid dispensing device or reservoir.

The passage 7 does not contain a valve, and has a female Luer-Lok fitting 29, adapted to receive the delivery end of the syringe S which pumps fluid through the T-connector. The syringe tip is shown in dashed lines in Figure 1.

The operation of the T-connector of Figure 1 is as follows. A piston-type syringe S is threaded into the Luer-Lok 29 at the end of passage 7, on the exterior of arm 4. Into the female Luer socket 19 is fitted a Luer fitting on the end of a tube leading to a container R (shown in dashed lines in Figure 1) containing a supply of fluid to be pumped. Onto male Luer fitting 13 is fitted a female Luer fitting of a needle N, for injection of the fluid into the body. Pumping action of the piston of the syringe on arm 4 draws fluid from the reservoir R into the interior chamber 30 in the housing 1 on the suction stroke, and then on the pumping stroke pumps this fluid through passages 8, 28 and 17 into and through the needle affixed to the Luer fitting 13. A volume of fluid is drawn from the reservoir equal to the capacity of the syringe attached to the arm 4, and this volume is injected with each stroke on the piston. It will be evident that a lesser volume can be drawn, if desired, and that the volume is completely controllable by the user, according to the length of the stroke of the piston.

The device can similarly be used to withdraw fluid from a body cavity. In this event, the needle or nozzle of the device is attached to the fitting 19 of arm 6, and the container or other receptacle attached to the fitting 13 of arm 5. Now, on the suction stroke, fluid is drawn out from the body cavity via passages 25, 27, and 9 and on the pumping stroke this fluid is pumped through passages 8, 28 and 17 into the receptacle.

It will be evident that the T-connector is readily fitted with any type of delivery mechanism, such as a Luer needle, nozzle, or other type of end piece, and that the T-connector can likewise be attached to any type of reservoir or receptacle. By the provision of standard couplings, standard delivery devices readily available in a hospital or doctor's office can be employed. At the same time, because of the small internal volume of the T-connector device, a high delivery pressure is obtained, and virtually no fluid is wasted with each use.

The actual capacity of the chamber 30 within check valve 15, externally of check valve 23, and externally of the syringe tip, including the volume of passages 7, 8 and 9, can be as little as 0.1 cc, or even smaller.

Any type of check valve can be employed. The duckbill-type of valve with bulbous duckbill tips shown in Figures 1 and 2 is preferred. There can also be employed poppet-type valves, ball-type valves, umbrella-type valves, and flap-type valves.

Figure 3 is a detailed view showing a coupling of the type of Figures 1 and 2 with umbrella valves in place of duckbill-type valves. The valves 40 and 41 have umbrella tops, and base flanges 42 and 43 connected to the umbrella portion by legs 44 and 45. The valves are fitted in the passages 46, 47, defined by reentrant portion 50 of the housing 51 and the end 52 of the fitting insert 53. The external face of wall portion 50 is a valve seat 54, against which the umbrella face of the valve seats, in a leak-tight seal. A similar valve seat is formed on the inner face of the fitting insert 53. The valves 40, 41 are held in the passages 46, 47 by the flanged bases 42, 43 of the valves, the valves close off the passages 48, 49 only when the umbrellas of the valves are seated against their respective valve seats. As a result, the valves control flow in the passages 55, 56, 57, 58, so that it proceeds only in the direction of the arrows.

In this T-connector each of the legs is provided with female Luer fittings 19.

Figure 4 shows a coupling in which flap valves 60, 61 are employed. The flap valve 61 is free to open inwardly into the passage 62, and the flap vlave is provided with a flange 63 which is held in place in a leak-tight seal by the inner face 65 of the fitting insert 64, in the recess 66 of the housing 67. Similarly, flap valve 60 disposed in passage 68 has a flange 74 which is held tightly in place by the inner face 75 of the fitting insert 70 in the recess 71, and the flap valve 60 is free to flap back and forth in the space afforded in the passage 69. The flap valves accordingly control flow through passage 72 of fitting insert 64, and

passages 62, 68 and 69, so that it proceeds only in the direction shown by the arrows.

The T-connector of Figure 4 has sockets 73 in the legs 5, 6 into which tubing, shown in broken lines, may be inserted, and a female Luer fitting in the leg 4.

The operation of the T-connectors of Figures 3 and 4 is exactly the same as in the T-connector of Figures 1 and 2.

While the arrangements shown of the valves in the arms and passages of the connectors are the preferred ones, so as to give the direction of flow shown in the Figures, it will be apparent that the twin valves can be placed in any two of the arms, for any desired direction of flow. The arrangement shown prevents the entrapment of air in the chamber of the coupling, and it also prevents the kinking of flexible hose or tubing which may be connected to the arms 2 and 3.

A special feature of the connectors of the invention is that it is possible to draw fluid from any closed container without the need of venting the interior of the container so as to relieve the vacuum that results. This is because of the extremely small internal volume of the T-connector. Due to the small internal volume (less than 1 cc and preferably less than 0.1 cc) a high compression ratio is obtained. This makes it possible to obtain pressures in a container of less than the vapor pressure of water and many other liquids. This means that no air need be introduced into a container to pump liquid out of the container. Thus, when the connector of the invention is employed, there is no danger of pumping contaminated air into a sterile liquid being pumped into the body.

In addition, it is possible to pump gases out of a container until extremely low pressures are reached. For example, with a valve having 0.1 cc. internal volume and a 50 cc. syringe, it is possible to pump a gas out of a container until a vacuum of 1/500 atmosphere is reached. Moreover, it is possible using a valve in accordance with this invention to pump gases with almost 100% volumetric efficiency.

The construction of the connector is such that it is possible to mold and cast it from any plastic that is thermoplastic or thermosetting but in a moldable or castable stage of polymerization. It can in fact be made easily in one unit from as few as five pieces, the coupling housing, the two valves, and two fitting inserts or valve insert pieces. If desired, the coupling housing also can be made in separate halves, and bonded together with the valves and socket adapters in place. The several parts can be permanently bonded together, by heat-sealing, integration of adjoining parts by fusing or solvent-bonding, or by an adhesive or bonding agent.

It may also be possible in some cases to mold the coupling housing in one piece, so that the valves can be inserted in their respective passages and sealed in place, with the ends of the passages being molded in the shape needed for reception of the desired types of connections. This reduces the total number of pieces to three; and eliminates the fitting insert pieces shown in the drawings.

The resulting device is simple, and easy to handle and clean. It is so inexpensive that it can be discarded after one use, for sanitary reasons. Since it can be entirely of heat-resistant and solvent-resistant material, it can be sterilized before use, and stored in a sterilizer for a considerable period of time, if desired, without deleterious effect.

It is possible to fabricate a coupling that is capable of withstanding the pressure necessary to pump from any type of container because the coupling can be formed by a molding or casting technique from nonresilient plastics materials with walls of a thickness to resist any fluid pressures that are likely to be encountered. In this respect, the nonresilient or rigid coupling of the invention is superior to couplings which have employed as a component of the construction a flexible tubing which incorporates the valves or connections to the pumping syringe or fluid supply.

WHAT WE CLAIM IS:—

1. A twin valve connector for coupling a syringe to a liquid medicament supply or a fluid receptacle, for delivery to or removal from a body via a fluid delivery device of a volume of liquid medicament or body fluid, respectively in excess of the capacity of the syringe, comprising, a coupling body of plastics material having three interconnected passages therethrough, check valves in two of said passages controlling flow of fluid therethrough in a single direction, the check valves having retaining means at an outer peripheral portion thereof, a fitting insert in each valve-containing passage, each fitting insert comprising a plastics material, the fitting insert extending into the said passage from the outside of the coupling body, and having a central passage therethrough for passage of fluid into and out from the connector, said valve retaining means being retained by the fitting insert and/or the coupling body and a peripheral portion of the fitting insert closely abutting an inner wall of the passage, and being either integrated with the plastics material of the coupling body, thereby obliterating any seam therebetween at that portion, or being bonded with the material of the coupling body, and forming a leaktight barrier, the fitting insert thus being retained in the coupling body in a permanent leaktight fit, and means at an outer portion of each passage adapted for connection of said

passage and the coupling body to a liquid medicament supply container, or a fluid receptacle, or a fluid delivery device or a syringe.

2. A twin valve connector according to claim 1, in which both coupling body and inserts are formed of the same plastics material.

3. A twin valve connector according to claim 1 or 2, in which the coupling body is molded in one piece, in a T-shape, with said three interconnected passages therethrough.

4. A twin valve connector according to claim 1, 2 or 3, in which the inserts are fitted in a recess in each passage so that the only surfaces thereof presented to fluid pressure are the side wall surfaces of the internal passages therethrough.

5. A twin valve connector according to claim 1, 2, 3 or 4, in which the check valves are each made of rubbery material, fixedly held in the passage in a leak-tight seal at one peripheral retaining portion thereof, and at another peripheral portion thereof engaging a valve seat or a further valve portion, and adapted to crack open in a flex-action movement away from the valve seat or further valve portion so as to open the passage.

6. A twin valve connector according to any preceding claim wherein the check valves are moveable in a flex-action movement at a peripheral portion thereof to engage a valve seat or a further valve portion in a relatively leak-tight planar seal, so as to close the passage, said check valve peripheral portion presenting a surface exposed and responsive to fluid pressure on each side thereof and being responsive to a fluid pressure on one side tending to bias said peripheral portion against the valve seat or further valve portion in a leak-tight seal therewith and thus prevent flow from that side, and being responsive to fluid pressure on the other side to move away from the valve seat or further valve portion and thus permit flow from that side at the crack-open pressure and thereafter.

7. A twin valve connector according to any preceding claim wherein the total open volume of the flow passages within the connector, including the space into which the valves open, is less than 1 cc.

8. A twin valve connector according to any preceding claim wherein the through passages and valves when open together define a smooth substantially uninterrupted flow path through the connector, all of the open passages being straightsided, allowing the venting of all air therewithin in at least one position of the connector.

9. A twin valve connector according to any preceding claim wherein the twin valves are duckbill valves having tapered walls diminishing in thickness from the neck to the bill of the valve.

10. A twin valve connector according to any one of claims 1 to 7, wherein the twin valves are umbrella valves.

11. A twin valve connector according to any one of claims 1 to 7 wherein the twin valves are flap valves.

12. A twin valve connector substantially as herein described with reference to the accompanying drawings.

ELKINGTON & FIFE,
Chartered Patent Agents,
High Holborn House,
52/54 High Holborn,
London, W.C.1,
Agents for the Applicants.

(8888) Printed by Her Majesty's Stationery Office Press, Edinburgh, 1971.
Published by The Patent Office, 25 Southampton Buildings, London, WC2A 1AY,
from which copies may be obtained.

1262146 COMPLETE SPECIFICATION
2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 1

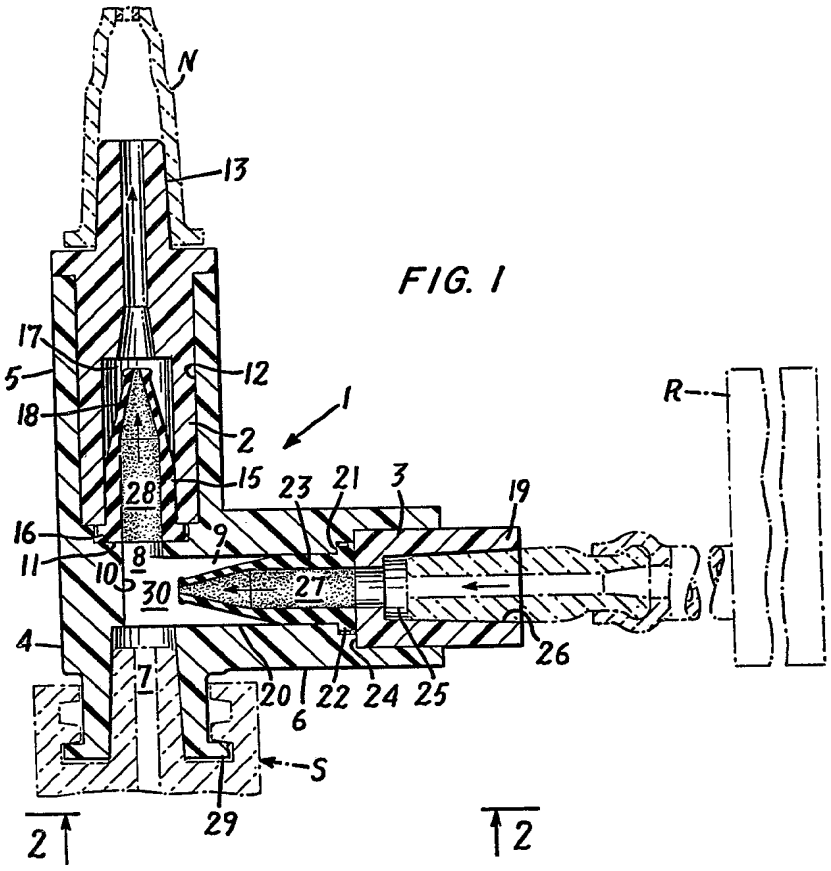

FIG. 1

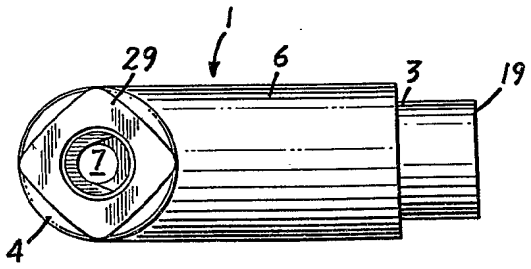

FIG. 2

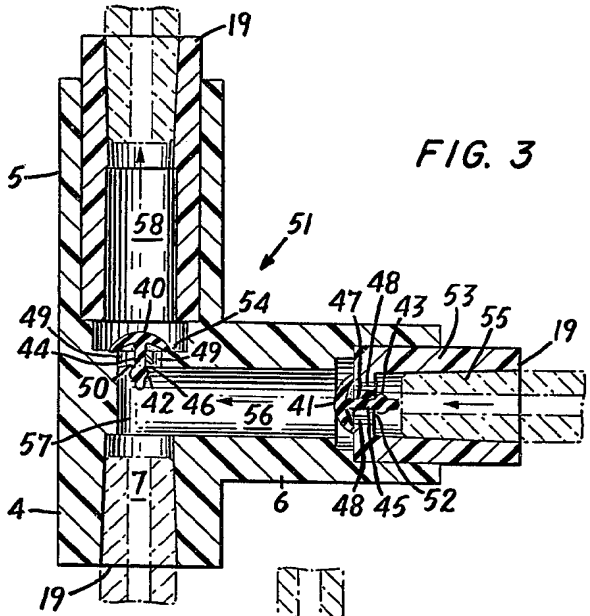
19
5
58
51
40
54
47
48
43
53
55
19
49
44
49
50
42
46
56
41
57
7
6
48
45
52
4
19

FIG. 3

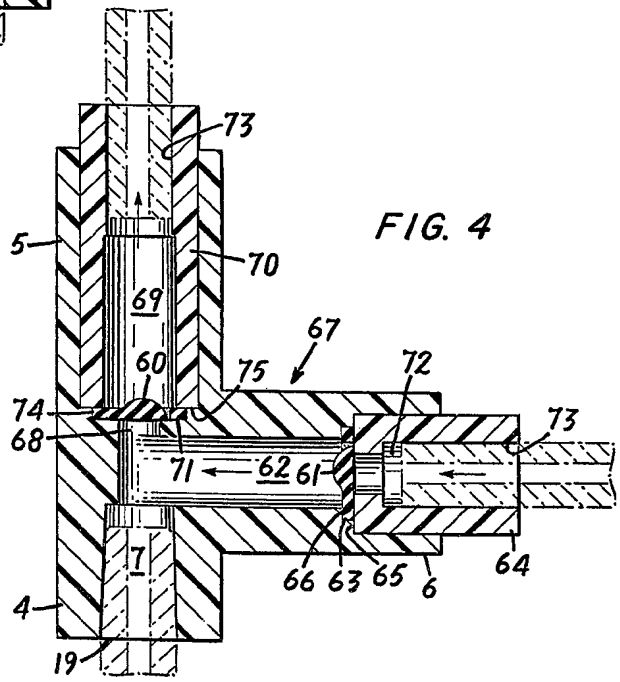
73
5
70
69
67
60
75
72
74
73
68
71
62
61
7
66
63
65
6
64
4
19

FIG. 4